Pharmacovigilance: A Review on Drug Safety and Monitoring

Dr. Allabaksha Shaikh, Shraddha Ganesh Dalvi

Abstract: **Pharmacovigilance is a vital discipline in healthcare that ensures the safety and efficacy of pharmaceutical products by systematically detecting, assessing, understanding, and preventing adverse drug reactions (ADRs). It plays a fundamental role in safeguarding public health by continuously monitoring drugs throughout their lifecycle, from clinical trials to post-marketing surveillance. This review comprehensively explores the core principles of pharmacovigilance, including its various types, essential applications, and the significant regulatory frameworks that govern drug safety across different regions.**

A key focus of this paper is the impact of pharmacovigilance in real-world settings, where post-marketing surveillance is crucial for identifying previously unrecognized ADRs that may not have been detected during pre-approval clinical trials. By analyzing pharmacovigilance studies on specific drugs, this review highlights the necessity of ongoing monitoring and reporting mechanisms that contribute to improving patient safety and therapeutic outcomes. The role of healthcare professionals, pharmaceutical industries, and regulatory authorities in ensuring effective pharmacovigilance systems is also discussed.

Moreover, the rapid advancements in technology, particularly the integration of artificial intelligence (AI), big data analytics, and machine learning, have significantly transformed pharmacovigilance practices. These modern tools have enhanced the efficiency and precision of ADR detection, enabling proactive risk assessment and early identification of potential drug-related hazards. As the field of pharmacovigilance continues to evolve, the adoption of innovative technologies and global collaborations remains crucial in reinforcing drug safety measures and minimizing risks associated with pharmaceutical therapies.

By shedding light on the dynamic landscape of pharmacovigilance, this review underscores the indispensable need for continuous monitoring and stringent regulatory oversight to protect public health and ensure the safe use of medicines worldwide.

Pharmacovigilance, the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems, is intrinsically linked to effective information management. The pivotal role of information in pharmacovigilance encompassing data collection, analysis, and dissemination for optimal patient safety. The foundation of pharmacovigilance lies in robust information system that facilitate the collection of adverse event reports from healthcare professionals, patients, and other stakeholder. The evolution of data sources, emphasizing the integration of electronic health records, wearable devices and real world evidence to enhance the depth and breadth of information available for analysis. Innovative technologies, including artificial intelligence and machine learning, are transforming pharmacovigilance by automating signal detection and predictive modeling. How those tools are utilized to sift through vast datasets, identifying potential safety concerns and aiding regulatory decision-making. Furthermore, the abstract delves into the importance of structured information sharing between regulatory agencies, pharmaceutical companies, healthcare providers. Timely transparent communication of safety information ensure a proactive response to emerging risk and enable the development of effective risk management strategies.

Keywords: **Pharmacovigilance, Drug Safety, Adverse Drug Reactions (ADRs), Post-Marketing Surveillance, Regulatory Frameworks, Artificial Intelligence, Big Data Analytics, Risk Assessment, Drug Monitoring, Patient Safety.**

1. INTRODUCTION

Pharmacovigilance is an essential discipline in clinical research, ensuring drug safety from clinical trials to post-marketing phases. Defined by the World Health Organization (WHO), pharmacovigilance involves the detection, assessment, understanding, and prevention of adverse drug effects. Given the increasing complexity of drug formulations and widespread global usage, pharmacovigilance has become indispensable in modern healthcare.

2. TYPES OF PHARMACOVIGILANCE STUDIES

Pharmacovigilance relies on various study designs to monitor drug safety:

- Spontaneous Reporting Systems (SRS): Healthcare professionals and patients voluntarily report ADRs.
- Intensive Monitoring Studies: Systematic patient monitoring for drug-related adverse effects.
- Cohort Studies: Longitudinal studies comparing drug-exposed and non-exposed groups.
- Case-Control Studies: Identifying risk factors by comparing affected patients with control subjects.

3. APPLICATIONS OF PHARMACOVIGILANCE

Pharmacovigilance has wide-ranging applications, including:

- Ensuring Drug Safety: Detecting rare or long-term ADRs post-marketing.
- Regulatory Decision-Making: Influencing drug recalls, black-box warnings, and usage restrictions.
- Public Health Protection: Identifying risks and recommending safer alternatives.
- Improving Drug Development: Enhancing safety profiles in clinical trials and beyond.
- Patient Awareness: Educating healthcare providers and patients on drug risks and benefits.

4. PHARMACOVIGILANCE STUDY OF SELECTED DRUGS

A pharmacovigilance study was conducted on multiple drugs to analyze their safety profiles:

- Metrose 500 Tablet: Used for type 2 diabetes mellitus; primary ADRs include gastrointestinal disturbances and potential lactic acidosis risk.
- Sitazee M 1000 Tablet: Combination therapy for diabetes; ADRs include hypoglycemia, nausea, and vitamin B12 deficiency.
- Dapazee M 1000 XR Tablet: Features dapagliflozin and metformin; ADRs include urinary tract infections, dehydration, and hypoglycemia.
- Glyzee M1 Tablet: A combination of glimepiride and metformin; risk factors include hypoglycemia and lactic acidosis.
- Metrose 500 SR Tablet: Extended-release metformin; primary ADRs include gastrointestinal issues and rare cases of lactic acidosis.
- Glyzee PM 2 Tablet: A combination of glimepiride, metformin, and pioglitazone; ADRs include edema, bone fractures, and weight gain.
- Glyzee 2 Tablet: Contains glimepiride, metformin, and pioglitazone; ADRs include hypoglycemia, nausea, and increased fracture risk.
- Glyzee M3 SR Forte Tablet: Combination of glimepiride and extended-release metformin; ADRs include gastrointestinal discomfort and hypoglycemia.
- Dapazee M 5/500 ER Tablet: A combination of dapagliflozin and extended-release metformin; ADRs include urinary tract infections, dehydration, and dizziness.
- Dapazee 10: An SGLT2 inhibitor for diabetes; ADRs include genital infections and urinary tract issues.

5. SUMMARY AND CONCLUSION

Pharmacovigilance is a dynamic process requiring collaboration between regulatory agencies, healthcare professionals, and pharmaceutical companies. Key aspects include data collection, signal detection, risk assessment, regulatory actions, and risk communication. The integration of artificial intelligence, big data, and electronic health records has significantly improved pharmacovigilance efficiency. Public awareness and education are crucial in enhancing ADR reporting and ensuring drug safety. Future advancements in pharmacovigilance promise to further refine drug monitoring, minimizing risks and enhancing patient care.

6. CONCLUSIN

Continuous Monitoring: Pharmacovigilance is an ongoing process that requires collaboration between regulatory agencies, healthcare professionals, and pharmaceutical companies.

Patient Safety: Ensuring drug safety through early detection and management of ADRs is essential to protect public health.
Regulatory Impact: PV studies guide regulatory decisions, leading to safer drug prescribing practices.
Technological Advancements: AI, big data, and electronic health records enhance the efficiency of pharmacovigilance systems.
Public Awareness: Educating healthcare professionals and patients about ADR reporting can improve drug safety.

7.0 REFERENCES

[1] Pipasha, B. , Arun , K.B.,„Setting standards for proactive pharmacovigilance in India : The way forward‟, Indian J pharmacol , 2007; 39(3): 124-128.
[2] Kumanan, R., Sudha, S., Vijayashre, P., Charumath, S., Gowridevi, K.C., Mahesh, M. Imperative Approach on pharmacovigilance in Indian systems of medicines, International journal of pharma sciences and Research (ijpsr), 2010; 1(9): 378-390.
[3] Deepa, A. „Pharmacovigilance obligations of the pharmaceutical companies in India India J pharmacol, 2008; 40: S13-S16.
[4] Zhengwu Lu.„information technology in pharmacovigilance : Benefits , challenges and future directions from industry perspectives‟, Drug, Health Care and patient safety, 2009; 1: 35-45.
[5] WHO, Pharmacovigilance: ensuring the safe use of medicines, Geneva: WHO 2004.
[6] WHO, Pharmacovigilance: ensuring the safe use of medicines, Geneva: WHO 2004.
[7] WHO, Pharmacovigilance: ensuring the safe use of medicines, Geneva: WHO 2004
[8] WHO, Safety of medicines in public health programmes : pharmacovigilance an essential tool, WHO, 2006.
[9] WHO, Safety of medicines in public health programmes : pharmacovigilance an essential tool, WHO, 2006.
[10] Yves snoeckx, m.pharm. : Pharmacovigilance for pharmacist, Johnson &Johnson 2006
[11] Barton, C., Silvey, J. „the internet and drug safety: What are the implications for pharmacovigilance‟, Drug Safety 1999; 20(2): 95-107.
[12] Don chin, Y., Seagull, FJ. „The hostile environment of the intensive care unit‟, curro pin critcare 2002; 8: 316-320.
[13] Department of CDSCO, Ministry of Health and Family Welfare, Government of India: Protocol for National pharmacovigilance program, November 2004.
[14] Edwards, A. ,Elwyn,G. „How should effectiveness of risk communication to aid patients decision be judged‟, A review literature. Medical Decision Makang 1999; 19(4): 128-434.
[15] Edwards, IR. „The accelerating need for pharmacovigilance‟, Journal of the Royal college of Physicians, 200; 34: 48-51
[16] International Drug Monitoring: The Role of National Centers (WHO Technical Report Series No .498) WHO.
[17] Lazarou J etal. „Incidence of ADR in hospitalized patients: A meta analysis of prospective studies‟, Journal of the American medical association, 1998; 279: 1000-1008
[18] Linquist AM. : seeing and observing in international pharmacovigilance, Uppsala WHO, centre for international drug Monitoring, 2003.
[19] Meyboom, RHB. , Egberts, ACG. Gribnau, FWJ. Hekster, YA. „Drug Safety: Pharmacovigilance in perspective‟, 1999; 21(6): 429-447.
[20] Mary,R. ,couper and shanthi pal :Quality assurance and safety of medicines ,WHO, Geneva 2008.
[21] Nair, MD. : The need for a formal system in india,avialiable at from pharmabiz.com.
[22] Sharma, B., Bhattacharya A., Gandhi, R., Jayshree Sood. , Rao, B.K. Pharmacovigilance in intensive care unit –An overview‟, Indian journal of Anesthesia, 2008; 52(4): 373-384.
[23] Sten Olsson. „Pharmacovigilance training with focus on India‟, Indian J pharmacol, vol.40, Feb., 2008; S28-S30.
[24] Talbot, JCC. , Nilsson, BS. „Pharmacovigilance in the Pharmaceutical industry‟, British Journal of Pharmacology 1998; 45: 427-431.
[25] Van Boxtel, CJ. , Santosa, B., Edwards, Ire. „Drug benefits and risks : International text Book Of Clinical Pharmacology, Johnwiley & Sons, chichester, 2001.
[26] WHO, Definition of pharmacovigilance, 2002.
[27] WHO Collaborating centre for International

Drug Monitoring: The importance of pharmacovigilance –Safety Monitoring of medicinal products: WHO publications, 2002

[28] Whitworth Dr. India „s pharmacovigilance system to monitor adverse reaction of drugs, available at the site of regulatory affairs focus magazine.

[29] WHO, Safety of medicines: A guide to decting and reporting adverse drug reactions, Geneva: WHO, 2002.